

Outcome of the conformity check of an Annex XV restriction dossier

Outcome of the conformity check of an Annex XV dossier proposing restrictions at EU level

Please see the Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals for further guidance on making the conformity check and its Annex on setting a clear scope developed by the Restriction Efficiency Task Force.

The Committees need to verify that the dossier contains information as specified in Annex XV of REACH (Article 69(4)).

The (co-)rapporteurs should check whether the information presented in the dossier is sufficient and adequate to satisfy the legal information requirements described in Annex XV of REACH based on an initial screening. However, (co-)rapporteurs are neither expected to check the quality of the data used in the dossier nor to check whether the justifications given are well-founded. A positive result of the conformity check does not take a stand on the quality of data included or on whether the action proposed in the dossier is justified.

Substance concerned:

1. Chemical name: Per- and polyfluoroalkyl substances (PFASs)
2. EC No.: -
3. CAS No.: -

Member State submitting the proposal for restriction:

Germany, the Netherlands, Sweden, Norway, Denmark

Final outcome of the conformity check by RAC & SEAC:

The dossier **conforms** to the requirements of Annex XV of the REACH Regulation.

Please note that the recommendations to the Dossier Submitter will follow at a later date.

The conformity check was conducted by:

Committee for Risk Assessment (RAC)

Rapporteur: SANTONEN Tiina

Co-rapporteur: GEOFFROY Laure

RAC decision on the outcome of the conformity check 16/03/2023:

Concerning required information:

- ☒ [x] The dossier conforms to the requirements of Annex XV of the REACH Regulation.
- ☐ [] The dossier does not conform to the requirements due to shortcomings in:
 - ☐ [] Proposed restriction
 - ☐ [] Information on hazards and risks
 - ☐ [] Information on alternatives
 - ☐ [] Justification that action is required on an EU-wide basis
 - ☐ [] Justification that the restriction is the most appropriate EU-wide action
 - ☐ [] Information on stakeholder consultations
 - ☐ [] Substance ID
 - ☐ [] Technical dossier

Committee for Socio-economic Analysis (SEAC)

Rapporteur: FANKHAUSER Simone

Co-rapporteur: COGEN Simon

SEAC decision on the outcome of the conformity check 10/03/2023:

Concerning required information:

- ☒ [x] The dossier conforms to the requirements of Annex XV of the REACH regulation.
- ☐ [] The dossier does not conform with the requirements due to shortcomings in:
 - ☐ [] Proposed restriction
 - ☐ [] Information on hazards and risks
 - ☐ [] Information on alternatives
 - ☐ [] Justification that action is required on an EU-wide basis
 - ☐ [] Justification that the restriction is the most appropriate EU-wide action
 - ☐ [] Information on stakeholder consultations
 - ☐ [] Technical dossier

Annexes to the outcome of the conformity check

Annex I: The conformity report template with details of the conformity check performed.

Annex II: The substance identity check report is annexed if more explanation is given.¹

¹ Delete if Annex II is not needed.

ANNEX I. CONFORMITY REPORT²

I. Check of the Annex XV report on: Per- and polyfluoroalkyl substances (PFASs)

A. Checking the proposed restrictions (RAC & SEAC)

- A1. Does the proposal specify the identity of the substance (or the substances, when relevant)? See Report section 1.1.1 and Annex B: B.1.

RAC: Yes ☒ No ☐

- A2. Does the proposal specify the scope of the restriction proposed (see Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals Appendix II for more detail on assessing the scope; the relevant part of the guidance should be taken into account when assessing this question)? See Report section 2.2 and Annex E: E.1.1.

RAC: Yes ☒ No ☐

SEAC: Yes ☒ No ☐

- A3. Does the proposal include a summary of the justifications for the restriction? See Summary and Report section 2.2.

RAC: Yes ☒ No ☐

SEAC: Yes ☒ No ☐

B. Information on hazards and risks (RAC)

- B1. Where there are other dossiers or chemical safety reports submitted under the REACH Regulation relevant for this restriction dossier, or relevant risk assessments submitted for the purposes of other EU legislation or other fora such as OECD:

- Does the report refer to the information on hazard or risks that has already been agreed in any of the aforementioned contexts?
- Does the report take into account information in those dossiers and reports³?

² It is important to bear in mind that the conformity check is not an evaluation of the dossier but is intended to ensure there is information to fulfil each requirement in Annex XV to ensure a meaningful assessment of the dossier can be undertaken.

³ This is to check that the requirement set in Article 69(4) of REACH is fulfilled in addition to demonstrating that the dossier conforms to the Annex XV requirements.

See Report section 1.1. and Annex B.

RAC: Yes ☒ **No** ☐

- B2. Does the report appear to allow an evaluation of whether the approach used to identify the hazard and risk is in accordance with Annex I of REACH? See Report section 1.1 and Annex B.

RAC: Yes ☒ **No** ☐

- B3. Does the report appear to present information to allow an assessment of the hazard(s)? See Report section 1.1. and Annex B: B.4.-B.8.

RAC: Yes ☒ **No** ☐

- B4. Does the report appear to present information on the uses of the substance(s) and resulting emissions or exposure? See Report section 1.1. and Annex B: B.9.

RAC: Yes ☒ **No** ☐

SEAC: Yes ☒ **No** ☐

- B5. Does the report appear to address the risks so to allow an assessment? See Report section 1.1. and Annex B: B.10.

RAC: Yes ☒ **No** ☐

- B6. Does the report appear to provide information that implemented risk management measures are not sufficient? See Report 1.1. and Annex B: B.9.1.

RAC: Yes ☒ **No** ☐

SEAC: Yes ☒ **No** ☐

C. Information on alternatives (RAC and SEAC)

- C1. Does the report appear to document whether or not any alternative substances or technologies have been identified and assessed? See Annex E: E.2.

RAC: Yes ☒ **No** ☐

SEAC: Yes ☒ **No** ☐

D. Justification that action is required on an EU-wide basis

- D1. Does the report appear to allow an evaluation of the reasons supporting action on an EU wide basis (rather than action at national or local level)? See Report 1.2 and Annex C.

RAC (for risk-related considerations): Yes ☒ **No** ☐

SEAC (for market-related considerations): Yes ☒ **No** ☐

E. Justification that a restriction is the most appropriate EU-wide measure

- E1. Does the report appear to allow an evaluation of the assessment of the proposed restriction and other identified RMOs against their effectiveness (including risk reduction capacity, costs and proportionality), practicality (including information and justification facilitating the assessment of enforceability, implementability and manageability) and monitorability? See Report section 2 and Annex E: E.5., E.7., and E.8.

RAC (for effectiveness regarding risk reduction capacity, practicality and monitorability): Yes ☒ No ☐

SEAC (for effectiveness regarding proportionality, practicality and monitorability): Yes ☒ No ☐

- E2. Does the assessment referred to in E1 appear to give sufficient background on the defined scope and conditions of the restriction , other than those issues covered by Question A2? See Report Section 2 and Annex E: E.7. and E.8.

RAC: Yes ☒ No ☐

SEAC: Yes ☒ No ☐

- E3. Does the assessment referred to in E1 appear to give estimates on the costs to the society due to the proposed restriction? See Report section 2. and Annex E: E.4.

SEAC: Yes ☒ No ☐

F. Socio-economic Assessment of Proposed Restriction

Socio-economic impacts of the proposed restriction may be analysed with reference to Annex XVI of the REACH Regulation, giving additional information to Section E. Such information comprises changes in employment or wider economic impacts (e.g. international trade or competition) as well as any additional information (other than that presented in part E) on economic, human health and/or environmental impacts.

G. Information on stakeholder consultation (RAC and SEAC)

G1. Does the report describe whether or not any stakeholder consultation has been conducted? See Annex G.

RAC: Yes ☒ **No** ☐

SEAC: Yes ☒ **No** ☐

II. Technical dossier

For hazard information that has not been previously submitted to ECHA, are Robust Study Summaries included which appear to include sufficient information allowing a review of the relevance, reliability and adequacy of the data of relevance for the proposed restriction?

RAC: Yes ☐ **No** ☐

Not applicable

ANNEX II. SUBSTANCE IDENTITY CHECK REPORT

Report on substance identity for Annex XV dossier

Substance name:	Per- and polyfluoroalkyl substances (PFAS)
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The identity of the substances falling within the scope of the proposed restriction has been defined in the restriction dossier in accordance with Annex XV of REACH.

The following information needs to be amended/clarified in the restriction dossier and/or its annexes:

- The scope of the proposed restriction would need some clarifications.
- Clarifications on the wording used in relation to polymers and polymerization should be included in the report.
- Other editorial suggestions have been proposed in the main report and in the Annexes in relation to substance identity and analytical methods.
- The extensive amount of information provided in the Annex XV dossier did not allow for a thorough assessment in a short time frame. Therefore additional comments will be provided if needed once the documents provided have been checked more carefully.